PCT WORLD INTELLECTUAL PROPERTY ORGANIZATION
International Bureau

INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification 5 : A61M 29/00 — A1

(11) International Publication Number: WO 91/01773

(43) International Publication Date: 21 February 1991 (21.02.91)

(21) International Application Number: PCT/IT90/00072

(22) International Filing Date: 26 July 1990 (26.07.90)

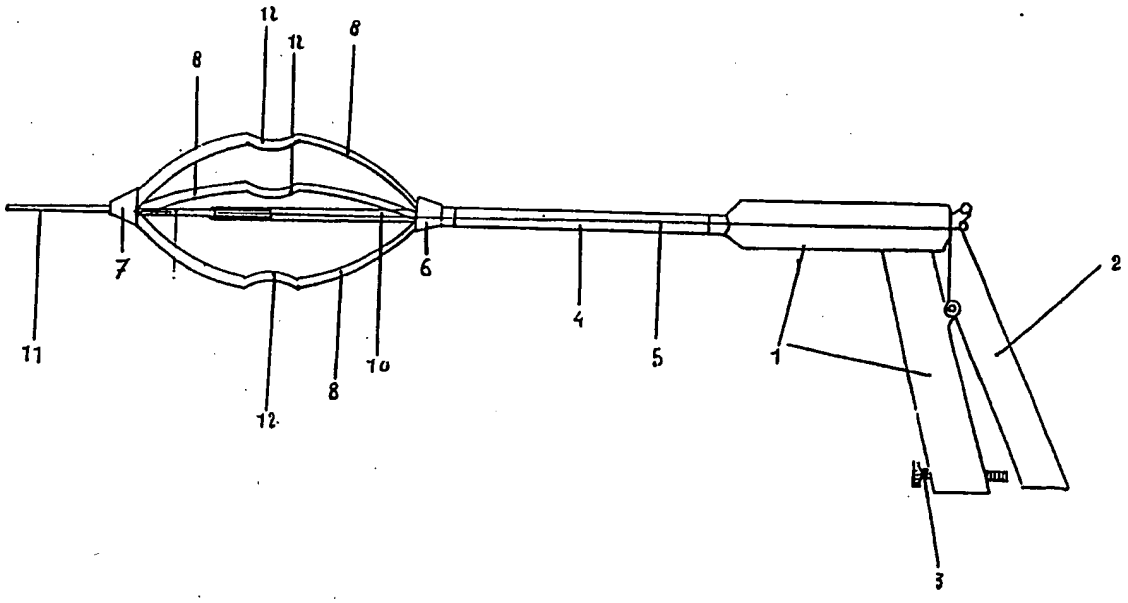
(30) Priority data:
35915 B/89 — 1 August 1989 (01.08.89) — IT
47824 A/90 — 3 April 1990 (03.04.90) — IT

(71)(72) Applicants and Inventors: MANGIERI, Enrico [IT/IT]; Via Parenzo, 1, I-00198 Roma (IT). D'ORAZI, Claudio [IT/IT]; Via P. Belon, 133, I-00169 Roma (IT).

(81) Designated States: AT (European patent), AU, BE (European patent), BF (OAPI patent), BJ (OAPI patent), BR, CA, CF (OAPI patent), CG (OAPI patent), CH (European patent), CM (OAPI patent), DE (European patent)*, DK (European patent), ES (European patent), FI, FR (European patent), GA (OAPI patent), GB (European patent), IT (European patent), JP, LU (European patent), ML (OAPI patent), MR (OAPI patent), NL (European patent), NO, SE (European patent), SN (OAPI patent), SU, TD (OAPI patent), TG (OAPI patent), US.

Published
With international search report.
Before the expiration of the time limit for amending the claims and to be republished in the event of the receipt of amendments.

(54) Title: PERCUTANEOUS MECHANICAL DILATING CATHETER FOR CARDIAC VALVES AND BLOOD VESSELS



(57) Abstract

This invention is a mechanical dilating catheter that serves to dilate stenotic cardiac valves and blood vessels. It is composed of four parts: 1) the handle (1); 2) the sheath (4); 3) the wire (5); 4) the dilating body. This has a concave area (12) in the central section of the expansion blades (8) which firmly anchors the body to the edges of stenotic cardiac valves and to stenotic segments of blood vessels.

* See back of page

DESIGNATIONS OF "DE"

Until further notice, any designation of "DE" in any international application whose international filing date is prior to October 3, 1990, shall have effect in the territory of the Federal Republic of Germany with the exception of the territory of the former German Democratic Republic.

FOR THE PURPOSES OF INFORMATION ONLY

Codes used to identify States party to the PCT on the front pages of pamphlets publishing international applications under the PCT.

AT	Austria	ES	Spain	MC	Monaco
AU	Australia	FI	Finland	MG	Madagascar
BB	Barbados	FR	France	ML	Mali
BE	Belgium	GA	Gabon	MR	Mauritania
BF	Burkina Fasso	GB	United Kingdom	MW	Malawi
BG	Bulgaria	GR	Greece	NL	Netherlands
BJ	Benin	HU	Hungary	NO	Norway
BR	Brazil	IT	Italy	PL	Poland
CA	Canada	JP	Japan	RO	Romania
CF	Central African Republic	KP	Democratic People's Republic of Korea	SD	Sudan
CG	Congo			SE	Sweden
CH	Switzerland	KR	Republic of Korea	SN	Senegal
CM	Cameroon	LI	Liechtenstein	SU	Soviet Union
DE	Germany	LK	Sri Lanka	TD	Chad
DK	Denmark	LU	Luxembourg	TG	Togo
				US	United States of America

Percutaneous mechanical dilating catheter for cardiac valves and blood vessels.

Great progress has been made in interventional cardiology over the last decade. The therapeutic use of balloon catheters has been extended to stenotic cardiac valves with the aim of increasing the flow of blood by dilating the valve. However, balloon catheters have certain limitations. This is due partly to their structure and conformation and partly to the fact that they can have a dilating effect on the valve only at the moment of maximum inflation of the balloon. Below, we outline some of the most common drawbacks associated with this type of catheter.

The first of these is serious hypotension with cerebral ischemia which occurs when the balloon is fully inflated and temporarily obstructs the flow of blood inside the valve undergoing dilation.

The second is the onset of cardiac valve insufficiency, which aggravates the original illness and necessitates valve transplantation within a fairly short timescale. This is due to the fact that the balloon must be inflated to its maximum capacity relatively quickly, in addition to the fact that it can only assume one shape regardless of the type of valve involved. A third drawback is the damage that can be caused by a balloon larger in diameter that the valve ring or the stenotic blood vessel being treated. Yet another drawback is the instability of the balloon within stenotic valves. It can slip on the surface of such structures, producing little or no dilation.

The aim of the percutaneous mechanical dilating catheter is to eliminate the serious drawbacks mentioned above. This new catheter solves the problem of how to dilate stenotic cardiac valves and blood vessels.

This catheter is undoubtedly an improvement on the existing balloon catheter for the following reasons;

a) unlike the balloon catheter, it allows an improved flow of blood during the process of dilation itself,thus avoiding the risk of serious systemic hypotension and ischemia.

b) the new catheter allows the dilating body to be positioned in the most anatomically favourable way inside the stenotic valve or vessel.

c) the cardiologist can regulate the dimensions of the body as required during the procedure.

d) the dilation prccedure can be carried cut in a much less traumatic manner without limitations of time and with maximum accuracy of pressure on the stenotic valve cusps and blood vessels.

e) the body of the new catheter can be firmly anchored to the edges of stenotic valves and to the stenotic segments of blood vessels.

From observation obtained during experiments on dead subjects, the inventors deduced that only the concavity on the central section of the expansion blades allows to firmly anchor the dilating body tc the edges of stenotic valves and to the tracts of blood vessels. Used in vivo without a firm anchorage, the dilating body would frequently lose contact with the stenotic structure, possibly providing little or no dilating effect.

DESCRIPTION

Fig. 1 shows the percutaneous mechanical dilating catheter. It comprises four parts; the handle, the sheath, the wire, and the dilating body. The diagram shows the catheter in the act of dilation. The handle 1 is pistol-shaped and is furnished with a lever 2. This transmits commands via a wire 5 to open and close the dilating body. At the bottom (lower extremity) of the handle there is a screw to regulate expansion 3. The flexible sheath 4 has a lenght and diameter which can be adjusted to suit the age and the surface area of the patient. The wire runs through the sheath and is attached at one end to the handle and at the other to a head 7 of the body. One end of the sheath is connected to the handle and the other to a head 6 of the body. The body, which is shown in the act of dilation, is made up as follows The two heads 6, 7 are located at each extremity of the body. Each head has three sites for the expansion blades 8. The proximal head 6 has a hole for the wire 5; the distal head 7 has an anchor point for the wire 5. Each of the heads is fitted with a tube 9, 10 which fit into each other and serve to regulate the movement of the heads. The wire runs through these tubes. At the end of the body there is a flexible guide 11 attached to the head 7. There is a concave area 12 located in the central section of the expansion blades 8.

MODE OF EMPLOYMENT

Pressure applied on the lever 2 modifies the position of the wire. This brings the two heads closer together, thus opening (flexing) the three blades. During this expansion, the blades come into contact with stenotic valves or blood vessels, which they then dilate as required. After dilation, the pressure on the heads is released allowing the body to return to its initial closed position.

CLAIMS

1. the "Percutaneous mechanical dilating catheter for cardiac valves and blood vessels" characterized by being composed of four parts; a handle, a sheath, a wire, a dilating body.

2. the "Percutaneous mechanical dilating catheter for cardiac valves and blood vessels", as preceding, having a dilating body.

3. the "Percutaneous mechanical dilating catheter for cardiac valves and blood vessels", as preceding, having a dilating body preferably made of stainless steel, but not excluding any other suitable material.

4. the "Percutaneous mechanical dilating catheter for cardiac valves and blood vessels", as preceding, having a dilating body comprising three flexible, elastic blades 8 preferably made of stainless steel, but not excluding any other suitable material.

5. the "Percutaneous mechanical dilating catheter for cardiac valves and blood vessels", as preceding, of which the blades 8 have a convave area 12.

6. the "Percutaneous mechanical dilating catheter for cardiac valves and blocd vessels", as preceding, of which the concave area 12 is located in the central section of the blades 8.

1-1

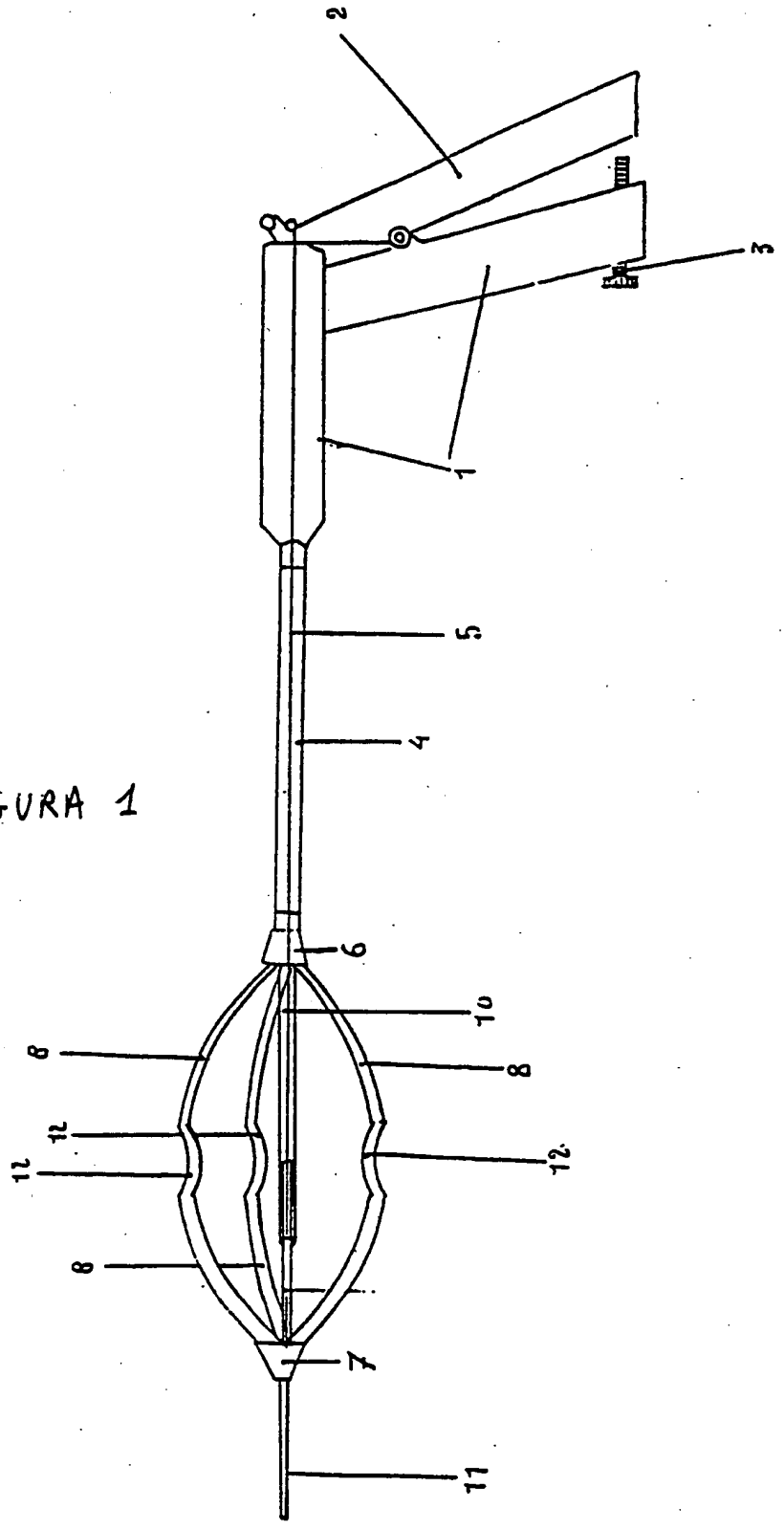


FIGURA 1

INTERNATIONAL SEARCH REPORT

International Application No PCT/IT 90/00072

I. CLASSIFICATION OF SUBJECT MATTER (if several classification symbols apply, indicate all) [6]

According to International Patent Classification (IPC) or to both National Classification and IPC

IPC[5]: A 61 M 29/00

II. FIELDS SEARCHED

Minimum Documentation Searched [7]

Classification System	Classification Symbols
IPC[5]	A 61 M, A 61 B

Documentation Searched other than Minimum Documentation to the Extent that such Documents are included in the Fields Searched [8]

III. DOCUMENTS CONSIDERED TO BE RELEVANT [9]

Category [10]	Citation of Document, [11] with indication, where appropriate, of the relevant passages [12]	Relevant to Claim No. [13]
X	DE, A, 1963316 (INSTITUT SEREDETSCHNO-SOSUDISTOI) 24 June 1971 see claims 1-3; figures 1-2	1-3
X	US, A, 3517128 (HINES) 23 June 1970 see claim 1; figures 1,4	1-4
X	US, A, 4648402 (SANTOS) 10 March 1987 see claim 1; figures 1-6	1-4
X	US, A, 1677671 (COUNCILL W.) 17 July 1928 see claims 1-6; figures 1-2,9	1-4

* Special categories of cited documents: [10]

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

IV. CERTIFICATION

Date of the Actual Completion of the International Search	Date of Mailing of this International Search Report
22nd November 1990	10 DEC. 1990
International Searching Authority	Signature of Authorized Officer
EUROPEAN PATENT OFFICE	MISS T. TAZELAAR

ANNEX TO THE INTERNATIONAL SEARCH REPORT ON INTERNATIONAL PATENT APPLICATION NO. IT 9000072 SA 38820

This annex lists the patent family members relating to the patent documents cited in the above-mentioned international search report. The members are as contained in the European Patent Office EDP file on 04/12/90 The European Patent Office is in no way liable for these particulars which are merely given for the purpose of information.

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
DE-A- 1963316	24-06-71	None	
US-A- 3517128	23-06-70	None	
US-A- 4648402	10-03-87	None	
US-A- 1677671		None	